

REMARKS

Reconsideration and withdrawal of the requirement for restriction are respectfully requested in view of the remarks herewith.

The Office Action required restriction under 35 U.S.C. §121 from among one of the following groups of inventions:

- Group I: Claims 1-17, and 28-32, drawn to a reverse genetics system and a recombinant plasmid comprising it, classified in class 536, subclass 23.1;
- Group II: Claim 18 drawn to a method for preparing a fully-infectious RNA transcript, classified in class 536, subclass 23.1;
- Group III: Claim 19 and 22-27, drawn to a method for preparing a cell line, classified in class 435, subclass 325;
- Group IV: Claims 20 and 21, drawn to a cell line stably replicating the reverse genetics system, classified in class 435, subclass 325;
- Group V: Claim 33, drawn to a method of identifying potential antiflaviviral chemotherapeutics, classified in class 424, subclass 184.1;
- Group VI: Claims 34-38, drawn to a method of collecting and transmitting a dataset, classified in class 710, subclass 717;
- Group VII: Claim 39, drawn to a pharmaceutical composition comprising the antiflaviviral chemotherapeutic, classified in class 424, subclass 184.1;
- Group VIII: Claim 40, drawn to a method for administering the pharmaceutical composition, classified in class 424, subclass 184.1;
- Group IX: Claims 41 and 42, drawn to a method for generating a potential attenuated WNV vaccine, classified in class 424, subclass 184.1;
- Group X: Claim 43, drawn to methods of generating a live attenuated WNV lineage I virus vaccine, classified in class 424, subclass 184.1;
- Group XI: Claim 44, drawn to method of treating a flaviviral infection, classified in class 424, subclass 184.1;
- Group XII: Claim 45-69, drawn to a DNA molecule, classified in class 536, subclass 23.1;
- Group XIII: Claims 70-79, and 89, drawn to a method for screening a plurality of compounds, classified in class 436, subclass 501;

- Group XIV: Claims 70, 91 and 92, drawn to a composition comprising the flavivirus inhibitor, classified in class 424, subclass 184.1;
- Group XV: Claims 80-88 and 90, drawn to a high throughput assay for screening, classified in class 436, subclass 501; and
- Group XVI: Claims 93 and 94, drawn to a cell line comprising the DNA molecule, classified in class 435, subclass 325.

Group I, claims 1-17 and 28-32, drawn to a reverse genetics system and a recombinant plasmid comprising it, classified in class 536, subclass 23.1, is provisionally elected, with traverse, for further prosecution in this application. Applicants reserve the right to file divisional applications to non-elected subject matter. Reconsideration and withdrawal of the requirement for restriction are respectfully requested in view of the remarks herewith.

Applicants further request a modification of the restriction requirement such that Group I claims are rejoined with, and thus searched and examined together with, the claims of Group II, drawn to a method for preparing a fully-infectious RNA transcript, and Group XII, drawn to a DNA molecule, since Groups I, II and XII share the identical search classification. Further, Applicants additionally request further modification of the restriction requirement such that the claims of Group I are further rejoined with the claims of Groups V, VI, IX, X, XIII and XV since the method claims in those Groups depend from and include the limitations of the reverse genetics system of Group I. Accordingly, Applicants respectfully submit that no serious burden would be placed on the Examiner to search and examine the claims of Groups I, II, V, VI, IX, X, XII, XIII and XV.

As a traverse, it is noted that the MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. MPEP § 803. Second, the examiner must examine the entire application on the merits “[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions.” *Id.* Accordingly, the MPEP directs the examiner to search and examine an entire application regardless of whether it includes distinct or independent inventions where no serious burden is placed on the examiner by the search and/or examination.

The Office Action alleges that “[b]ecause these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes is proper.” (See page 5 of the Office Action).

However, this statement is contradicted by the fact that many of the Groups of claims, including those mentioned above, share identical search classifications.

For example, Groups I, II and XII, as noted above, have all been classified under class 536, subclass 23.1. As another example, Groups II, IV and XVI have all been classified under class 435, subclass 325. Additionally, Groups V, VII, VIII, IX, X, XI and XIV are commonly classified under class 424, subclass 184.1. And, Groups XIII and XV are both classified under class 436, subclass 501. The fact that these sets of Groups are identically classified necessarily indicates that search and examination of at least those claims commonly classified would be coextensive and thus, there would not be an undue burden placed on the Examiner. Therefore, it is respectfully submitted that at least a subset of the Groups that are commonly classified should be subject to rejoinder.

Moreover, all of the claims taken together as originally filed and presented herein represent a web of knowledge and continuity of effort that merits search and examination as a single invention. The invention as disclosed in the present application relates broadly to a novel reverse genetics system, and methods for making and using the reverse genetics system, especially a lineage I WNV cDNA or replicon system, which can be used to screen for novel antiflaviviral chemotherapeutics or vaccines that are effective to treat or immunize against flavivirus infections, such as, WNV. The claims of the invention all require, relate or involve the reverse genetics system and thus each claim is inextricably linked under the same inventive concept.

For example, the reverse genetics system can be introduced into a cell line (e.g., claim 21) or be used in a screening assay (e.g., claims 70 or 80). Further, the reverse genetics system may be used to identify potential antiflaviviral chemotherapeutics (e.g., claim 33) and to generate attenuated WNV vaccines (e.g., claims 41 and 43). An embodiment of the reverse genetics system includes a DNA molecule encoding a mRNA of lineage I WNV genome (e.g., claim 45). Accordingly, it is respectfully asserted that each of the claims of the present application fall within the same inventive concept and thus, search and examination of the entire application would not be unduly burdensome on the part of the Examiner.

Specific comments as to the individual asserted grounds for restriction presented in the Office Action are as follows.

The assertion in the Office Action that the claims of Group I are distinct from those claims of Groups II, IX and X and that restriction is proper is misguided. As noted above, the claims of Group I and II are both classified under the same class (536) and subclass (23.1) and therefore search and examination of Group I claims would necessarily be coextensive with and would encompass claim 18 of Group II. Moreover, since the claims of Group II and Group IX are dependent from the reverse genetics system of claim 5 of Group I, it does not seem logical that Groups II and IX should be restricted from the claims of Group I. In addition, since the claims of Group X relate to an embodiment of the reverse genetics system, i.e. the lineage I WNV cDNA clone, they are inextricably linked to the inventive concept of the elected Group I claims. Accordingly, as the claims of Groups I, II, IX and X are overlapping under a unified inventive concept, search and examination of Group I claims would necessarily encompass Groups II, IX and X. Therefore, it is respectfully submitted that search and examination of all four Groups together would not impose a serious burden on the Examiner.

The Office Action states that the claims of Groups I, IV, VII, XII, XIV, XV and XVI would require unrelated searches of the prior art. It is respectfully submitted that any search of the claims of Group I would certainly encompass references for the subject matter of the claims of Groups IV, VII, XII, XIV, XV and XVI as each of the groups overlaps with the unified inventive concept of the invention, namely the novel reverse genetics system. Indeed, the reverse genetics system of the invention or an embodiment thereof, which can include a DNA molecule encoding a mRNA of a lineage I WNV genome (e.g., Group XII), can be inserted in a cell line and used to screen for antiflaviral compounds (e.g., see claims of Groups IV, VII and Group XIV). In addition, many of the claims of the different Groups have identical classification. For example, Groups I and XII (536, 23.1), Groups VII and XIV (424, 184.1) and IV and XVI (435, 325) are classified with the identical class and subclass designations. Therefore, it is respectfully submitted that search and examination of the claims of Group I together the Group IV, VII, XII, XIV, XV and XVI claims would not place an undue burden on the Examiner.

The Office Action contends that the claims of Group III (method of preparing cell line) and IV (cell line) are distinct and thus, restriction is proper. Applicants respectfully assert, however, that any search for the subject matter of the claims of Group III would certainly encompass references relevant to the claims of Group IV, and vice versa. First, the claims of

Group III and Group IV are classified under the same class and subclass of inventions and thus, necessarily a search of either set of claims would encompass the other. Further, as the claims of both Groups III and IV involve a stably replicating reverse genetics system of the invention, search of Group I claims would certainly encompass the claims of Groups III and IV. Therefore, Applicants respectfully submit that it would not impose any serious burden on the Examiner to search and examine both Groups of claims (III and IV) or Group III and IV claims together with Group I claims, as Groups III and IV have identical classification and overlap the subject matter of Group I with respect to the reverse genetics system of the invention.

The Office Action asserts that the claims of Groups VII and XIV are distinct from the claims of Groups V, VI, VIII, XI and XIII. It is respectfully submitted that any search for the subject matter claim of Groups VII and XIV would certainly encompass references for the subject matter of the claims of Groups V, VI, VIII, XI and XIII. Indeed, the claims of Groups VII, XIV, V, VIII and XI are classified as having an identical class and subclass. Thus, a search of any one of the claims of Groups VII, XIV, V, VIII and XI would necessarily encompass all the claims within those Groups. Further, a search of any of the claims of Groups VI and XIII would encompass the claims of the other Groups as all the claims, and together with the claims of Group I, are unified under the same inventive concept involving the reverse genetics system of the invention. For example, the method claims of Group XIII use the reverse genetics system of the invention in a screen for compounds with antiflaviral properties. And, the method of the claims of Group VI relates to the collecting and transmitting of data produced by a screening method that utilizes the reverse genetics system of the invention. Accordingly, a search of any claim of the Groups VII and XIV would certainly encompass any of the claims under the Groups V, VI, VIII, XI and XIII, as well as with Group I claims, as many of the claims have the identical classification and all the claims are unified under the same inventive concept. Thus, it is respectfully submitted that search and examination of the Groups above would not place any serious burden on the Examiner.

The Office Action contends that the claims of Groups V, VI, VIII, IX, XI and XIII are distinct. However, it is respectfully submitted, as presented above, that any search for any claim within these Groups would certainly encompass any other claim within those Groups as many of the claims have the identical classification (see Groups V, VII, IX, XI) and all of the claims are related and are overlapping as involving the same inventive concept that is the reverse genetics

system of the invention. Accordingly, it is respectfully submitted that search and examination of the Groups above would not place any serious burden on the Examiner.

The Office Action states that the claims of Group XIII and XV are distinct. It is respectfully submitted, however, that any search for the claims of Group XIII would encompass those claims of Group XV, and vice versa. Indeed, the claims of Group XIII and those of Group XV have the identical class and subclass designations and thus, any search of the claims would necessarily encompass the remaining claims of those Groups. Further, the subject matter of the claims of both Groups involve the reverse genetics system of the invention. Specifically, the Group XIII and Group XV claims are directed to screening methods that utilize the reverse genetics system of the invention of an embodiment thereof. Further, as the claims of both Groups XIII and XV involve the reverse genetics system of the invention, a search of the claims of Group I would certainly encompass the claims of Groups XIII and XV. Accordingly, Applicants respectfully submit that search and examination of the claims of Groups XIII and XV or the claims of Groups XIII and XV together with the claims of the elected Group I, would not place any serious burden on the Examiner.

Accordingly, as Applicants have elected the claims of Group I, with traverse, Applicants request that Group I be rejoined with those Groups similarly classified, such that the claims of Groups I, II and XII are searched and examined together. Applicants additionally request further modification of the restriction requirement such that the claims of Group I are also rejoined with the claims of Group V, VI, IX, X, XIII and XV, most of which are identically classified under class 424, subclass 184.1 (V, IX, X) or under class 436, subclass 501 (XIII and XV), in view of the fact that the method claims in those Groups depend from and include the limitations of the reverse genetics system of Group I.

In view of the remarks herein, enforcing the present restriction requirement would result in inefficiencies and unnecessary expenditures by the Applicants and the PTO, as well as extreme prejudice to Applicants (particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed). Restriction has not been shown to be proper, especially in view of the requisite showing that a serious burden has not been met. Indeed, the search and examination of each commonly classified Group would likely be co-extensive and, in any event, would involve such interrelated art that search and examination of the entire

application can be made without undue burden on the Examiner. All of the preceding, therefore, mitigate against restriction.

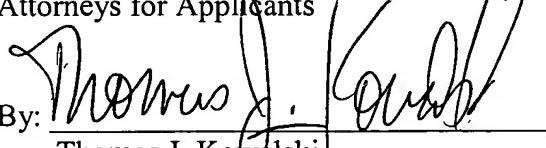
In view of the foregoing, Applicants respectfully request reconsideration and withdrawal, or at least modification, of the restriction requirement, such that, at the least or at least a portion thereof of the claims of Groups II, V, VI, IX, X, XII, XIII and XV are searched and examined together with the claims of provisionally elected Group I. And, it is especially requested that Groups I and V be examined together for the herein reasons.

CONCLUSION

Reconsideration and withdrawal, or modification of the restriction requirement, and a prompt and favorable examination on the merits, is respectfully requested.

Respectfully submitted,

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